

REMARKS

Claims 61-70, 72-82, and 84-85, 87-98 and 100 presently appear in this case. Claims 84-100 have been withdrawn from consideration. No claims have been allowed. The Office Action of August 24, 2010, has now been carefully studied. Reconsideration and allowance are respectfully urged.

Briefly, the present invention relates to a method for transfecting a cell with a nucleic acid molecule. To do so, the cell is contacted with a sphingoid-polyalkylamine conjugate together with the nucleic acid molecule. The sphingoid-polyalkylamine conjugate has the formula defined by formula (I) in the claims.

The examiner states that claims 84-100 have been withdrawn from further consideration as being drawn to nonelected inventions. The examiner says that the election was made without traverse. However, the present amendment now places the elected claims in condition for allowance. It is the structure of the compound used that is the special technical feature that warrants allowance of the elected claims. As all of the non-elected claims share this special technical feature, it is appropriate for the examiner to now reconsider the lack of unity rejection and consider and allow all of the claims now present in the case, regardless of

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whether or not the initial lack of unity rejection was traversed. There may not have been a common special technical feature at the time, but there is now.

Claims 61-62 and 65-82 have been rejected under 35 USC 102(e) as being anticipated by Barenholz (US2008/0112917). The examiner says that Barenholz has an earlier effective filing date and thus constitutes prior art under 35 USC 102(e). This rejection is respectfully traversed.

The present application and the Barenholz publication claim the same earliest effective filing dates and thus the Barenholz publication is not available as a reference. Please note that the ADS filed on December 15, 2005, in this case (and visible in Public PAIR), as well as the Declaration filed May 5, 2006, list the same four provisional applications as are listed in the Barenholz publication. For some unknown reason, these four provisional applications were not listed on the Official Filing Receipt received in this case and are not listed in the Continuity Data on Public PAIR. Accordingly, another ADS (identical to the one already filed in 2005) is attached hereto. It is requested that the records of the PTO be corrected so as to list the provisional applications from which the present application claims benefit.

Accordingly, the Barenholz publication is not based on an application filed before the effective U.S. filing date of the present application and cannot be available as a reference under 35 USC 102(e). Reconsideration and withdrawal of this rejection is therefore respectfully urged.

Claims 61-62 and 65-70 have been rejected under 35 USC 102(b) as being anticipated by Jorgensen (US2002/0188023). The examiner states that Jorgensen teaches a composition comprising lipid-polyalkylamine conjugates and that the lipid that Jorgensen teaches is ceramide. The examiner states that the polyalkylamine that Jorgensen teaches includes spermine and spermidine and that Jorgensen also teaches that the lipid-polyalkylamine conjugate can be linked using a hydrocarbyl group, including carbamoyl. The examiner states that Jorgensen also teaches the claimed sphingoid-polyalkylamine conjugate and that the compounds of their invention can be used in formulations for gene therapy, which involves introduction of foreign nucleic acid into cells, i.e., transfection, so that its expressed protein may carry out a desired therapeutic function. The examiner also states that Jorgensen discloses a composition comprising an admixture with a condensed polypeptide/nucleic acid complex to provide a non-viral nucleic acid delivery vehicle, and that the compound is a cationic liposome that can be used to facilitate delivery of

therapeutic agents such as DNA, mRNA, antisense oligonucleotides, proteins and drugs into cells. This rejection is respectfully traversed.

Claim 61 has now been amended so as to insert the subject matter of dependent claim 71. Thus, claim 61 is now the same as claim 71 rewritten into independent form. As claim 71 was not subject to this rejection, the rejection has now been obviated. Reconsideration and withdrawal thereof are therefore respectfully urged.

Claims 61-70 have been rejected under 35 USC 103(a) as being unpatentable over Jorgensen or Barehholz in view of Wheeler. The examiner states that Wheeler teaches lipopolyamine compositions comprising nucleic acid for use in methods involving the transfer of nucleic acid into cells, and that Wheeler specifically teaches that exogenous nucleic acid such as dsRNA, dsDNA, ssRNA, ssDNA, and cloned DNA in the form of a vector, such as a plasmid or viral genome, may be combined in a transfection complex. Thus, the examiner considers it to have been *prima facie* obvious to include plasmid or siRNA nucleic acid with the lipid-polyalkylamine conjugates of either Barenholz or Jorgensen. The examiner states that one of ordinary skill in the art at the time the invention was made would have been motivated to do so to facilitate the delivery of these molecules into cells and

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would have had a reasonable expectation of success for doing so because Jorgensen discloses that lipid-polyalkylamine conjugates are effective to facilitate delivery of drugs into cells. This rejection is respectfully traversed.

Claim 61 has now been amended so as to insert the subject matter of dependent claim 71. Thus, claim 61 is now the same as claim 71 rewritten into independent form. As claim 71 was not subject to this rejection, the rejection has now been obviated. Reconsideration and withdrawal thereof are therefore respectfully urged.

It is submitted that all of the claims now present in this case fully comply with 35 USC 112 and fully define over the references of record. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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